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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,283	07/08/2003	Peter T. W. Cheng	LA0085 NP	9913
23914	7590	07/26/2004	EXAMINER	
STEPHEN B. DAVIS BRISTOL-MYERS SQUIBB COMPANY PATENT DEPARTMENT P O BOX 4000 PRINCETON, NJ 08543-4000			AULAKH, CHARANJIT	
			ART UNIT	PAPER NUMBER
			1625	
DATE MAILED: 07/26/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/616,283

Applicant(s)

CHENG ET AL.

Examiner

Charanjit S. Aulakh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3 and 5-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3 and 5-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. According to paper filed on June 1, 2004, the applicants have canceled claims 2 and 4 and furthermore, have amended claims 1, 6, 8, 9, 12, 13, 15 and 16. The applicants have also submitted a new abstract.

2. Applicant's election of group I in papers filed on June 1, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse; see MPEP 818.03(a).

3. The applicants have submitted new abstract. However, this abstract is also too long since it contains two pages. The abstract should contain only one page.

Response to Arguments

4. Applicant's arguments filed on June 1, 2004 have been fully considered but they are not persuasive regarding enablement rejection and objection due to inclusion of non-elected subject matter. The applicants have amended claims to overcome indefiniteness rejections and furthermore, the examiner agrees with the applicant's arguments regarding definiteness of terms ---prodrug and stereoisomer---- since there are several examples present in the specification showing these two terms. The applicants are requested to check a minor typographical error in claim 1 for definition of variable B where it represents (CH₂)_x. Should it be x4?

In regard to enablement rejection, the examiner does not agree with the applicants arguments that specification is enabling for treating all disease conditions mentioned in claims 15 and 16. The applicants argue that it would be apparent to one skilled in the

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art that –modulation –refers to decreasing glucose levels, triglyceride levels, fatty acid levels while increasing insulin levels. The examiner does not agree with this argument. First of all, there are no working examples present showing any of these effects (decreasing glucose levels, triglyceride levels or fatty acid levels while increasing insulin levels) in the specification. Secondly, there is no mention of any mechanism (such as inhibition of some enzyme, receptor etc.) in the specification for the instant compounds. The utility for treating any disease condition is based on either prior art knowledge of a known mechanism or some experimental evidence in the instant specification. The instant specification does not meet these two criterias. Also, instant claim 15 is directed to treating diabetes or hyperglycemia (by virtue of decreasing blood glucose levels) and also to treat hyperinsulinemia (by virtue of decreasing insulin secretion). However, according to definition of modulation by the applicants, modulation refers to increasing insulin levels (see page 11 of arguments). It is not clear how one can treat hyperinsulinemia with a compound which itself increases insulin levels. There is no clear teaching in the specification whether the instant compounds decrease or increase blood glucose levels, triglyceride levels, fatty acids and insulin levels. The utility of the instant compounds will be different based on specific effects of instant compounds on the levels of blood glucose, triglycerides, fatty acids and insulin levels and definitely involves undue experimentation to validate this effect of hundreds of thousands of compounds covered by formula of instant claim 1.

In regard to objection of claims containing non-elected subject matter, the applicants mention that the claims are amended to delete non-elected subject matter (see last

lines 5 lines on page 13 of arguments). However, it is not true. According to restriction, in the elected group I, A represents (CH₂)₂-O, 5-membered ring consists of only 1,2,4 oxadiazole or 1,2,3 triazole and Y represents COOH.

Conclusion

5. Rejection of claims 1, 3 and 5-19 under 35 U.S.C. 112, first paragraph is maintained for the reasons of record.
6. Objection of claims 1, 3, 5-12 and 14-19 for containing non-elected subject matter is maintained for the reasons of record.
7. Rejection under 35 U.S.C. 112, second paragraph is now withdrawn in view of amendments and persuasive arguments.
8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

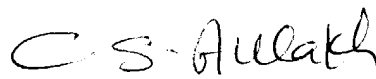
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is (571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Charanjit S. Aulakh
Primary Examiner
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